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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,746	03/24/2004	Lauren O. Bakaletz	28335/39196A	6532
4743 7590 01/19/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER GRASER, JENNIFER E	
			ART UNIT 1645	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS		MAIL DATE 01/19/2007		DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.	Applicant(s)	
10/807,746	BAKALETZ ET AL.	
Examiner	Art Unit	
Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Election 12/4/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 4/25/05,7/12/04&11/3/05
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claims 3, 4 and 5 (original claims 4, 5 and 6), SEQ ID No: 7, in the reply filed on 12/4/06 is acknowledged. The traversal is on the ground(s) that Groups II and VII should be examined together since they may be entitled to rejoinder of the method claims of Group VII if the products of Group II are found to be novel. This is not found persuasive because, as pointed out in the Restriction Requirement, Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide can be used in a method of detection which is a materially different process of using the product than in methods of eliciting an immune response. The Examiner did state that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

However, because the inventions of Groups II and VII are distinct for the reasons set forth in the Restriction Requirement and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search required for the Groups is not coextensive, restriction for examination purposes as indicated is proper.

Original claim 6 (now claim 5) has been placed in elected Group II. It was inadvertently left out of the original Restriction.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1, 2, and 6-18 are withdrawn from consideration because they are drawn to a non-elected invention.

### ***Specification***

2. The disclosure is objected to because of the following informalities: in the 'Brief Description of Figures' on page 27 of the specification, 'Figure 2' should be changed to 'Figure 2A and 2B' and 'Figure 3' should be changed to 'Figure 3A and 3B' in order to avoid a printer error at the time of issue.

Appropriate correction is required.

***Claim Objections***

3. Claims 3-5 are objected to because of the following informalities: they contain non-elected subject matter. The claims should be amended to only refer to the elected sequences, e.g., 'encoded by SEQ ID NO: 1' in claim 3 and 'comprising the amino acid sequence set forth in SEQ ID NO: 7' for claim 4. Additionally, claim 3 depends on a non-elected claim and should be amended. Appropriate correction is required.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it is unclear what is encompassed by a fragment thereof'. A fragment can read on as little as one amino acid. It is unclear which portions of the nucleic acid comprising SEQ ID NO: 7 will encode the generic 'fragment'. The metes and bounds of the invention cannot be understood. Clarification and/or correction is requested.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischmann et al (Science. 1995. 269: 496-512. and UniProt\_7.2\* database, Accession No. P45285) in view of Wood (Guide to Molecular Cloning Techniques. Vol. 152. 1987. Section IX. Chapter 49, pages 443-457).

Fleischmann et al disclose the amino acid sequence of a protein from H.influenzae which is 98.6% identical to Applicant's SEQ ID NO: 7. The sequence is disclosed to be 'peptide transport periplasmic protein' named 'sapA'. The polypeptide set forth in SEQ ID NO: 7 is taught by Applicants to be a dipeptide transport periplasmic protein also referred to as 'sapA'. The instant claims encompass fragments which do not require the full-length (100% match) SEQ ID NO: 7. Fleischmann et al teach the complete genome of H.influenzae Rd. Although the amino acid sequence represented in the computer database is a constructive reduction to practice, Fleischmann et al do not actually teach an isolated polypeptide/fragment.

Wood discloses techniques for gene cloning based on long oligonucleotide probes. It is disclosed that the most commonly used technique for gene cloning has been to utilize oligonucleotide probes based on protein sequence data (page 443, first paragraph). This technique requires at least a portion of the amino acid sequence to be

determined so that one can use it to infer the corresponding DNA (page 443, first paragraph). Based on the amino acid sequence information, either short or long oligonucleotide probes can be synthesized chemically. It is disclosed that the utility of the long, single sequence probes has been used repeatedly for the screening of high-complexity libraries starting with any stretch of protein sequence data (page 444, first full paragraph).

Several methods were notoriously well known in the prior art for obtaining the DNA which encodes a known protein sequence and it would have been obvious to use any of them in order to obtain the DNA for the protein disclosed by Fleischmann in order to recombinantly produce the protein. For example, the DNA could be obtained by PCR amplification of the sequence corresponding to sapA disclosed by Fleischmann. Alternatively, one could clone the protein by generating probes based on the protein sequences as taught by Wood described above, or, even simply deduce a degenerate DNA sequence from the recited amino acid sequence. The insertion of this sequence into a vector for recombinant production in a host bacterial cell was notoriously well known in the prior art at the time the invention was made and one of ordinary skill in the art would have been motivated to do so to investigate this protein for research activities and for its transport activity or as a diagnostic reagent. When producing the protein/fragments, the composition would inherently have a pharmaceutically acceptable carrier, e.g., water.

Prior Art made of record, not relied on:

Art Unit: 1645

8. Satola et al (Infect. Immun. 2003. 71: 7202-7207). Satola et al teach a transport protein from H.influenzae which is 75.6% identical to Applicant's SEQ ID NO: 7.

Status of Claims:

9. No claims are allowed. 'An isolated polypeptide consisting of SEQ ID NO: 7'; 'An isolated polypeptide encoded by a nucleic acid sequence set forth in SEQ ID NO: 1'; and 'A composition comprising an isolated polypeptide consisting of SEQ ID NO: 7 and a pharmaceutically acceptable carrier' are free of the prior art.

10. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser  
Primary Examiner  
Art Unit 1645



11/4/07